UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,237	07/24/2001	Sean E. Egan	3477-89	4932

20792 7590 09/16/2004

MYERS BIGEL SIBLEY & SAJOVEC
PO BOX 37428
RALEIGH, NC 27627

EXAMINER	
DAVIS, MINH TAM B	
ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 09/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/674,237	EGAN ET AL.	
	Examiner	Art Unit	
	MINH-TAM DAVIS	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 July 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,7-51 and 54-58* is/are pending in the application.

4a) Of the above claim(s) *11-18,20-49 and 54-58* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,7-10,19,50 and 51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant cancels claims 2-6, 52-53.

Accordingly, claims 1, 7-10, 19, 50-51 are being examined.

This application contains claims drawn to an invention nonelected with traverse in Paper of 09/30/03. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

The following are the remaining rejections.

REJECTION UNDER 35 USC 101, UTILITY

Rejection under 35 USC 101 of claims 1, 7-10, 19, 50-51 pertaining to lack of a specific, substantial asserted utility or a well established utility remains for reasons already of record in paper of 01/20/04.

Applicant argues that expression of the claimed polynucleotides of SEQ ID NO:1 and 2 blocks endocytosis in Cos-1 cell cultures, and that the encoded Ese1 protein of SEQ ID NO:3 binds to proteins known to be necessary for endocytosis. Applicant asserts that these findings provide a basis for further studies of the control of endocytosis by Ese, which is a real world utililty.

Applicant asserts that the specification also predicts the binding of Ese proteins to the HIV NEF protein, known to induce endocytosis, and thus the specification teaches a real utility for Ese in studies for intervention into HIV binding.

Applicant's arguments set forth in paper of 07/20/04 have been considered but are not deemed to be persuasive for the following reasons:

It is clear that further experimentation is required to show that the claimed polynucleotides or the encoded polypeptide thereof has practical use, and as noted by Applicant, further studies of the control of endocytosis by Ese is needed.

Concerning possible binding to HIV-NEF to the SH3 domain of Ese1, in view that HIV-NEF binds to SH3 domains, and induces coated pit formation, one cannot predict that HIV-NEF actually binds to Ese1 because the SH3 domain is small and the configuration or the conformation of the amino acids surrounding the SH3 domain could have significant effect on which proteins would fit into the conformation for binding to said SH3 domain. For example, although the SH2 domain of PLC gamma and GAP binds to tyrosine phosphorylated epidermal growth factor, and platelet-derived growth factor in vitro, it does not bind the tyrosine phosphorylated colony-stimulating factor 1 receptor (Muller et al, 1992, Mol Cell Biol, 12: 5087-5093, especially, page 5087, first column, last three lines bridging second column, page 5090, second column, last paragraph). Further, even if HIV-NEF binds to Ese1 via the SH3 domain, there is no data teaching as to what effect that binding would have. Thus it clear that further experimentation is required to determine whether the claimed Ese polynucleotides or the encoded polypeptide thereof would actually intervene with HIV binding to a cell.

Moreover, although the encoded Ese1 protein of SEQ ID NO:3 binds to proteins known to be necessary for endocytosis, there is no data teaching as to what effect that binding would have, and that further experimentation is required to determine whether

the claimed Ese polynucleotides or the encoded polypeptide thereof would actually have practical use.

Similarly, further experimentation is required to determine whether the claimed Ese1 polynucleotides or the encoded polypeptide would be useful for diagnosis or treatment of diseases, such as cancer, because there is no correlation between the claimed Ese1 polynucleotides or the encoded polypeptide and any diseases, and because change in the level of expression of a polynucleotide in a disease, such as cancer, which could be used for diagnosis, is not predictable as taught by Stanton et al, lehle et al, and Abbaszadegan et al, all of record, and because treatment of diseases, such as cancer, is unpredictable, as taught by Gura, Jain et al, Curti et al, Hartwell et al, all of record.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, ENABLEMENT

Rejection under 35 USC 112, first paragraph of claims 1, 7-10, 19, 50-51 pertaining to lack of support by a specific, substantial asserted utility or a well established utility remains for reasons already of record in paper of 01/20/04.

The same arguments and reasons for rejection set forth above under 101 rejection apply here as well.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, WRITTEN DESCRIPTION

Rejection under 35 USC 112, first paragraph of claims 1, 9-10, 19 pertaining to lack of a clear written description remains for reasons already of record in paper of 01/20/04.

Applicant argues that the claims have been amended to recite specific nucleotide sequences, and to recite complete complementary sequence, and thus the rejection is obviated.

Applicant's arguments set forth in paper of 07/20/04 have been considered but are not deemed to be persuasive for the following reasons:

The amended claim 1 now recites on a nucleotide sequence at least 80% or 90% identical to SEQ ID NO:1 or 2, and a complete complement thereof.

The claims encompass variants of SEQ ID NO:1 or 2, of unknown structure, having deletion, substitution or addition at any nucleotides, provided they are 80% or 90% similar to SEQ ID NO:1 or 2.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, SCOPE

If Applicant could overcome the above 101 and 112, first paragraph rejection, claims 1, 9-10, 19 remain rejected under 35 USC 112, first paragraph, because the specification while being enabling for SEQ ID NO:1 or 2, is not enabled for a nucleotide sequence at least 80% or 90% identical to SEQ ID NO:1 or 2, for reasons already of record in paper of 01/20/04.

Applicant argues that the claims have been amended to recite specific nucleotide sequences, and to recite complete complementary sequence, and thus the rejection is obviated.

Applicant's arguments set forth in paper of 07/20/04 have been considered but are not deemed to be persuasive for the following reasons:

The amended claim 1 now recites on a nucleotide sequence at least 80% or 90% identical to SEQ ID NO:1 or 2, and a complete complement thereof.

The claims encompass variants of SEQ ID NO:1 or 2, of unknown structure, and function, having deletion, substitution or addition at any nucleotides, provided they are 80% or 90% similar to SEQ ID NO:1 or 2.

In view of the unpredictability of protein chemistry, which applies as well to polynucleotide sequences which encode proteins, as taught by Bowie et al, Burgess et al, Lazar et al, Tao et al and Gillies et al, all of record, one would not know how to make the claimed polynucleotides such that they would function as claimed.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, SCOPE, NEW REJECTION

If Applicant could overcome the above 101 and 112, first paragraph rejection, claim 8 is still rejected under 112, first parargraph for the use of SEQ ID NO:1 or 2 or a complete complement thereof as a primer.

It is noted that claim 7, to which claim 8 depends, has been amended to a complete complement of SEQ ID NO:1 or 2.

Due to the amendment of claim 7, a 112, first paragraph rejection of claim 8, concerning the use of SEQ ID NO:1 or 2 or a complete complement thereof as a primer, is necessitated.

It is noted that SEQ ID NO:1, the coding sequence of SEQ ID NO: 2, and the complete complement thereof are full length polynucleotide sequences.

It is further noted that a primer is conventionally used for priming a reaction such as PCR, and that normally primers are only fragments of a polynucleotide sequence (Sambrook et al, eds, 1989, Molecular Cloning, A laboratory manual, 2nd ed, Cold Spring Harbor Laboratory Press, Cold Spring Harbor, p.14.2-14.3).

Thus since that SEQ ID NO:1, the coding sequence of SEQ ID NO: 2, and the complete complement thereof are full length polynucleotide sequences, it is not clear how they could be used as a primer.

In view of the above, it would be undue experimentation for one of skill in the art to practice the claimed invention.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JEFFREY SIEW can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Susan Ungar
Primary Patent Examiner

MINH TAM DAVIS

September 09, 2004